

Safeguarding public health

MHRA

The Yellow Card Scheme & Patient reporting

Jane Moseley
MHRA

Content

The MHRA logo is a dark blue oval with the letters 'MHRA' in white, sans-serif font.

- Yellow card scheme: rationale and evolution
- Development of patient reporting: why and how
- Patient reporting: data
- What happens to patient yellow cards: our processes
- Next steps for patient reporting

Pharmacovigilance

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- Known limitations of clinical trials at authorisation
- Vital to monitor
 - the safety of all medicines post-licensing
 - from all data sources including spontaneous reports
- MHRA objectives
 - Capture promptly the reports of adverse drug reactions
 - Initiate timely and appropriate action to protect public health

The Yellow Card Scheme

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- Vital public health mechanism
- Essential component in MHRA's pharmacovigilance work
- Scheme started in 1964 following the thalidomide tragedy
- To date, more than 500,000 UK reports submitted
- Reports submitted *in confidence* by healthcare professionals and patients

The Yellow Card Scheme

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- Reports also received via pharmaceutical companies, based on their legal obligations
- Reports can be made on prescription, OTC and GSL medicines, and alternative therapies (including herbals)
- We ask for reports of suspicions and look for signals
- Scheme not used for audit or disciplinary purposes

The Evolving Scheme

Extensions to Scheme:

- Coroners (1969)
- Pharmacists (April 1997 & Nov 1999)
- Nurses, midwives and health visitors (2002)
- NHS Direct patient reporting pilot scheme (2003)
- Patient reporting pilot scheme UK-wide (2005)

Today, reports can be submitted by:

- Paper Yellow Card form
- Electronic Yellow Card form on www.yellowcard.gov.uk
- *Telephone*

Taking the Yellow Card Scheme into the future

*“Report of an Independent Review of Access to the
Yellow Card Scheme” April 2004*

Made recommendations to:

- Incorporate patient reporting of suspected ADRs through the Yellow Card Scheme
- Open access to Yellow Card Scheme data, especially for public health research
- Strengthen the Yellow Card Scheme by increasing quantity and quality of reports



Patient reporting of suspected ADRs

Recommendations to enable patients to report suspected ADRs through the Yellow Card Scheme were immediately accepted by the Government, with Health Minister Lord Warner saying:

“Patients want and deserve to play their full part in making medicines safer... By introducing direct patient reporting we will improve the scheme even further”.

Why enable patients to report?

- Direct access to patients' views
- International experience: patients can be quicker to report than HCPs
- People want the opportunity to more actively contribute to medicine regulation
- More choice, greater access to medicines
- Increased use of medicines without healthcare professional supervision
- Growth in use in unconventional products (including herbal remedies)

Commonly cited concerns to Patient Reporting

No real evidence exists to support the commonly-cited concerns of Patient Reporting:

- increase in noise
- overload of systems
- unnecessary diversion of MHRA staff time
- usefulness of suspected ADR reports that have not been medically validated
- potential for system to be undermined (especially through organised reporting campaigns)

The Committee on Safety of Medicines' Patient Reporting Working Group

Created as a Working Group of CSM to advise the MHRA and CSM on:

- development of patient reporting pilots and systems
- communication and promotion of patient reporting
- evaluation of patient reporting

Working Group first met in September 2004

Wide representation with lay, academic, pharmacist and medical members

Designing a patient reporting system

The critical considerations for a patient reporting system:

- ✓ Easy for members of the public to understand, access and use
- ✓ Provide the information needed to effectively monitor medicine safety and provide better information for patients and health professionals

Gathering information

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Initial pilot – launched in January 2005

Discussion groups with:

- patients and representatives of patient organisations
- professional organisations

Presentations given to Working Group by:

- voluntary organisations
- NHS and healthcare organisations
- WHO
- communications experts

Review of international experience

Initial Pilot: From January 2005

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- To provide initial insights into patient reporting and inform design of UK-wide pilot
- Paper patient Yellow Card in 4000 GP surgeries across UK
- Web based patient Yellow Card on **www.yellowcard.gov.uk**
- All patient reports handled in the same way as health professional reports

Results of initial pilot

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- Over 650 patient reports between January-October 2005
- Averaged over 50 patient reports per month
- Internet Yellow Card reporting most preferred way of reporting
- Majority of Yellow Card reports were received from female reporters

Who completed Yellow Card reports: initial Pilot

<i>Reporter</i>	<i>Number of reports (%)</i>
Patients	520 (87.4%)
Parents	41 (6.9%)
Carers	25 (4.2%)
Partners/Spouses	5 (0.8%)
Relative	3 (0.5%)
On behalf of someone else (not specified)	1 (0.2%)

The UK-wide pilot for patient reporting of suspected side effects through the Yellow Card Scheme

- Launched in late-October 2005
- Designed to gauge effectiveness of different reporting mechanisms before finalised systems are put into place
- Awareness campaign underway

The UK-wide patient pilot

MHRA

Reports on suspected side effects can be made by patients on a Yellow Card

- ✓ 750,000 Yellow Cards are now available in a wide range of outlets, including:
 - *Community pharmacies throughout UK*
 - *GP surgeries throughout UK*
 - *NHS Hospital Pharmacies throughout UK*
 - *Mental Health Care Trusts*
 - *Patient and voluntary organisations*
- ✓ Reply-paid envelope built-in to Yellow Card
- ✓ In DL leaflet size
- ✓ Can be downloaded on the Yellow Card website, to print out and complete

YC scheme & patient reporting
Jane Moseley

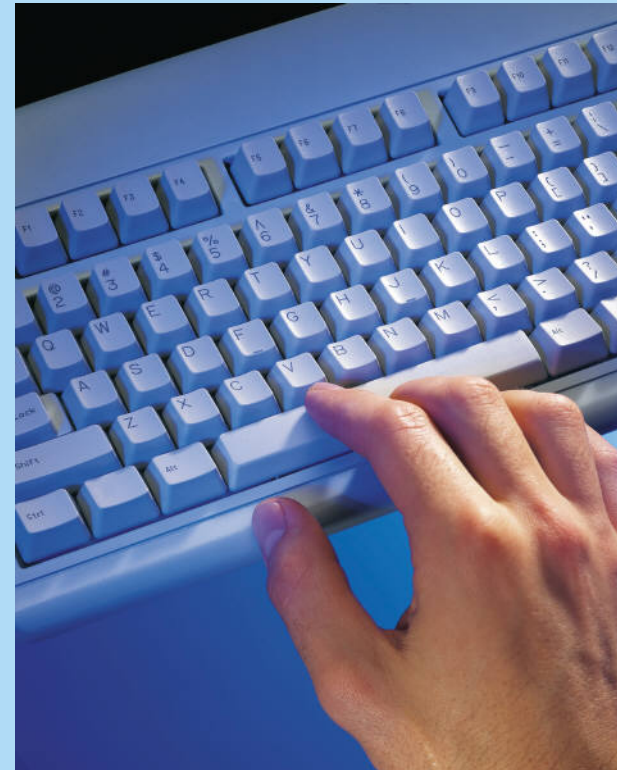


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The UK-wide patient reporting pilot

Reports on suspected side effects can be made by patients on the internet

- ✓ Web-based Yellow Card available at www.yellowcard.gov.uk
- ✓ Web-based Yellow Card is secure and information sent directly to the MHRA
- ✓ All members of the public can download anonymised, aggregated information on specific Yellow Card reports submitted on the Yellow Card website



The UK-wide patient reporting pilot

Reports on suspected side effects can be made by patients by telephone

- ✓ Reports taken over the telephone by the Yellow Card Hotline on **0808 100 3352**
- ✓ Yellow Card Hotline is a freephone service
- ✓ Yellow Card Hotline staffed by MHRA information staff



Who can report?

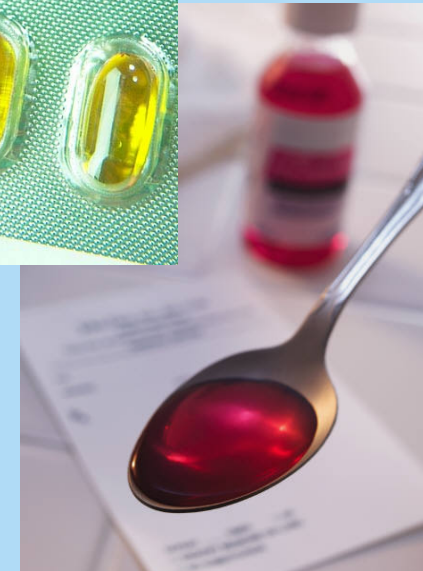
- ✓ Any member of the public
- ✓ Must provide name and contact details
- ✓ Reports can be made on others (e.g., by a parent or carer)
- ✓ MHRA will follow up reports whenever necessary with reporter



On which medicines can people report?

Reports can be made on suspected side effects from any medicine on the market:

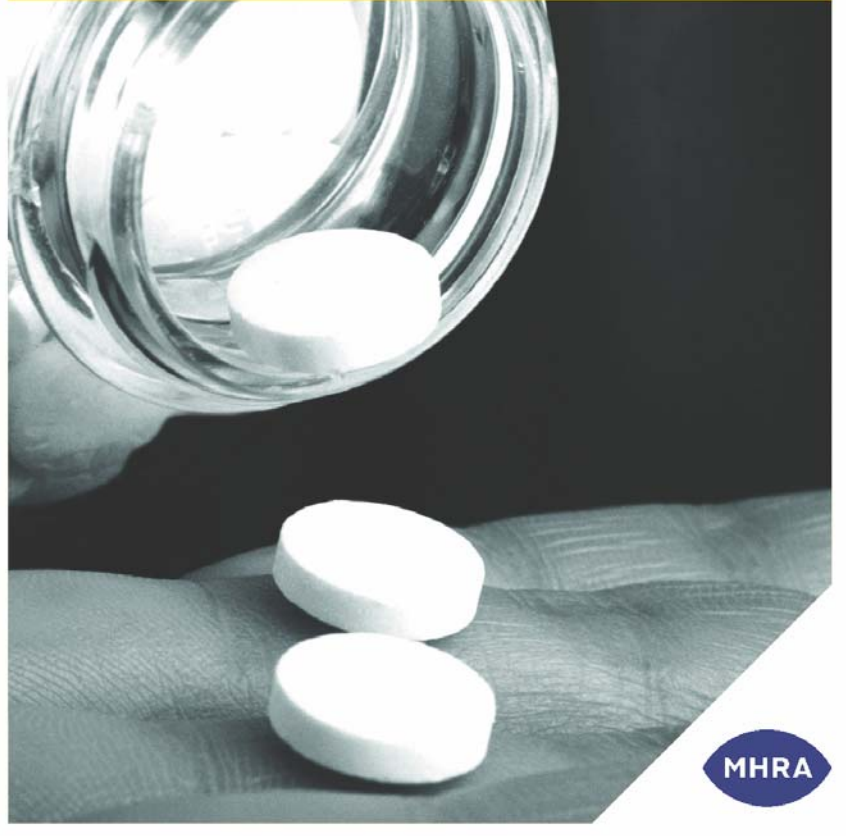
- ✓ prescribed medicines
- ✓ OTC medicines
- ✓ complementary remedies (including herbals)



YellowCard™
Helping to make medicines safer

**A side effect
from your medicine?**

Report it on a Yellow Card – available here or
report it on the web at www.yellowcard.gov.uk



YellowCard™
Helping to make medicines safer

Better understanding the impact of ADRs on the lives of patients

Patients provide different insights into suspected ADRs than health professionals, including:

- Richer descriptions of ADR experiences
- Information about the impact on the person's life and lifestyle
- Tendency to describe “symptoms” rather than “diagnoses”

This information will be useful in developing patient information and advice that is more meaningful, in patients own language

Better understanding the impact of ADRs on the lives of patients

About the suspected side effect

6 When did the suspected side effect start?
.....

7 How bad was the suspected side effect? (Tick one)

- Mild or slightly uncomfortable
- Uncomfortable, a nuisance or irritation, but able to carry on with everyday activities
- Bad enough to affect everyday activities
- Bad enough to be admitted to hospital
- Life-threatening
- Caused death

8 How is the person who had the suspected side effect now? (Tick one)

Recovered completely

.....

Recovered but with some lasting effects
(please describe below)

.....

Getting better Still has reaction Other
(please describe below)

.....

9 Please describe the suspected side effect and any treatment received, and tell us whether the suspected side effect caused the person to stop taking the medicine. Please attach separate sheets if necessary.

.....

.....



Promoting awareness of the Yellow Card Scheme

- MHRA is working with key professional and patient stakeholders
- Outlets receive posters to display “Yellow Cards – available here”
- Major media campaign to increase awareness

PRACTICE
Yellow Cards explained to public
 A campaign promoting the reporting of adverse drug reactions by patients has

Each pharmacist has Yellow Cards, an

Patient ADR reporting

A UK-wide pilot has started of “yellow card” reporting of suspected adverse drug reactions. The results are becoming clear: “Patients provide a different and extremely useful insight into suspected

Patients to report drug side effects

PATIENTS are now able to directly report side-effects from drugs to the medicines watchdog as part of a UK-wide pilot.

The Yellow Card Scheme, used by health staff and pharmaceutical companies to report suspected adverse reactions to medicines, will now be extended to the public.

Yellow card reporting forms will be

available in pharmacies, GPs' surgeries and other NHS sites across the UK from next week.

Suspected side-effects can also be reported online at www.yellowcard.gov.uk or by calling freephone 0800 100 3352.

The UK-wide trial follows successful pilots which have been running in parts of the UK since January.

Keep yellow cards at hand

Periodic attempts are made to increase the number of reports of adverse drugs. The original yellow card scheme was exclusive to doctors included (p537).

YC scheme & patient Jane Moseley

Yellow Card system goes nationwide after patients' positive response

PATIENTS across the UK can now report any side effects of drugs that cause

rashes to convulsions and even death. In January,

Regulatory Agency. It is pleased with the response so

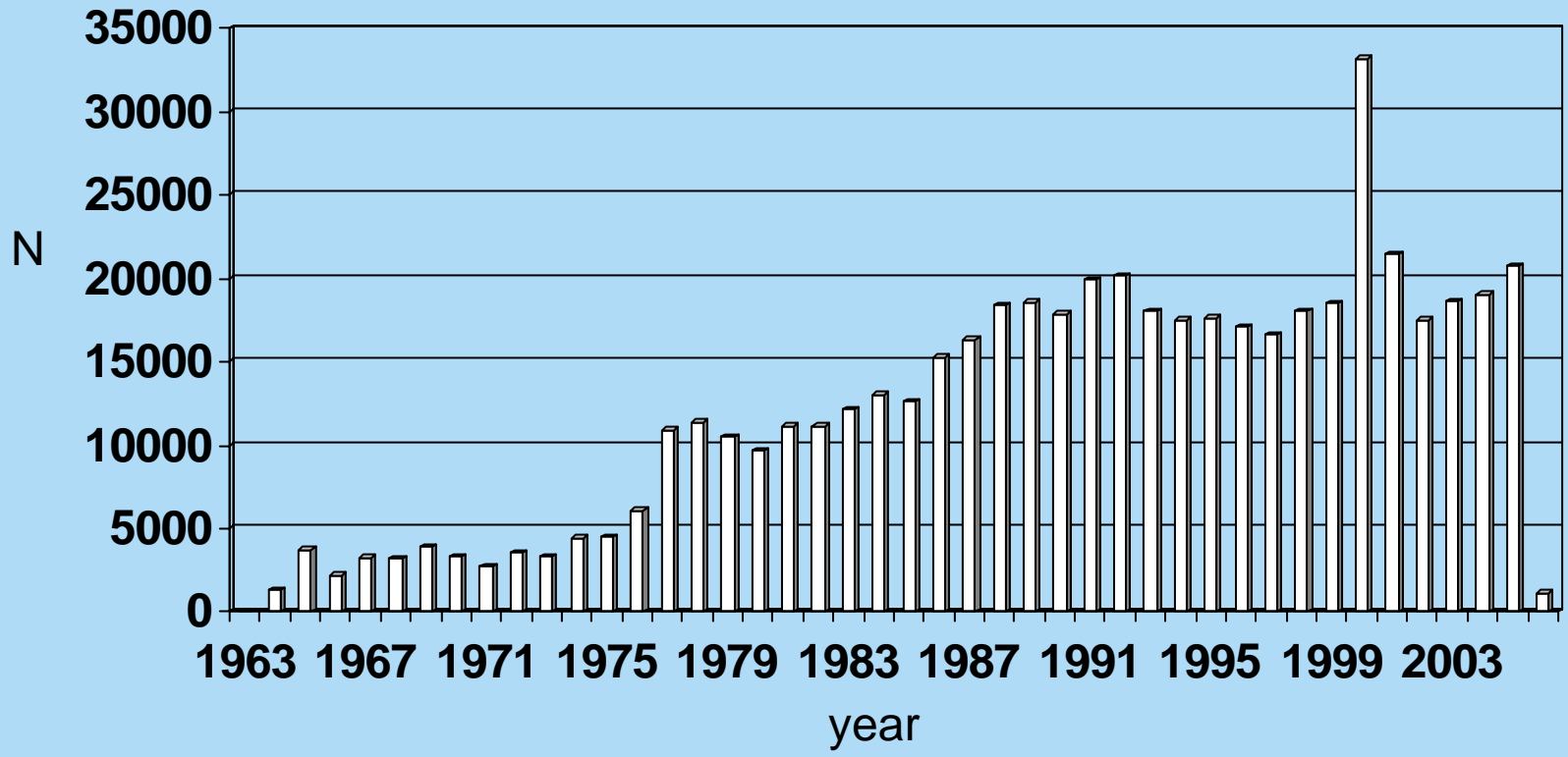
From this week, patients across the country will be

Slide 26
03/07/2006

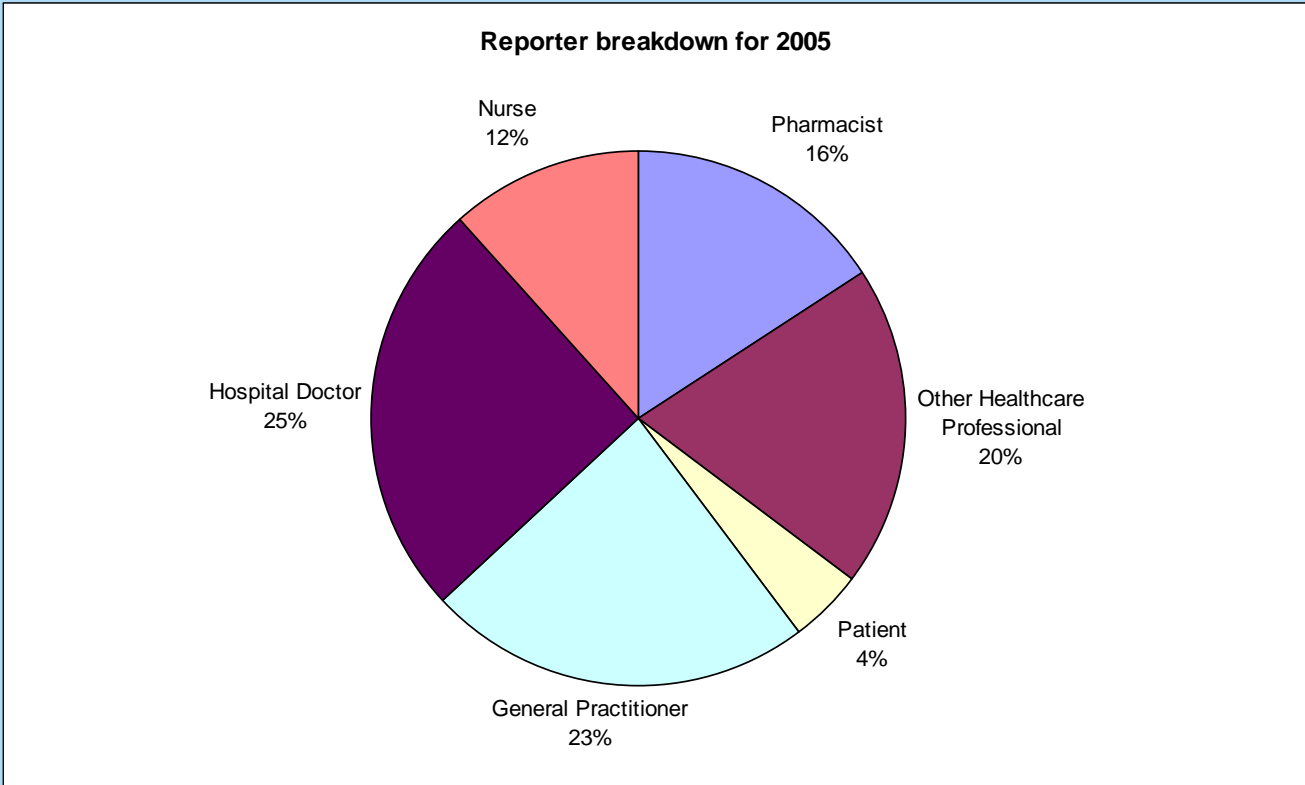
Reports by year UK data



(*N* ~ 530,000)



Reporting sources of ADR reports



Number of patient reports received

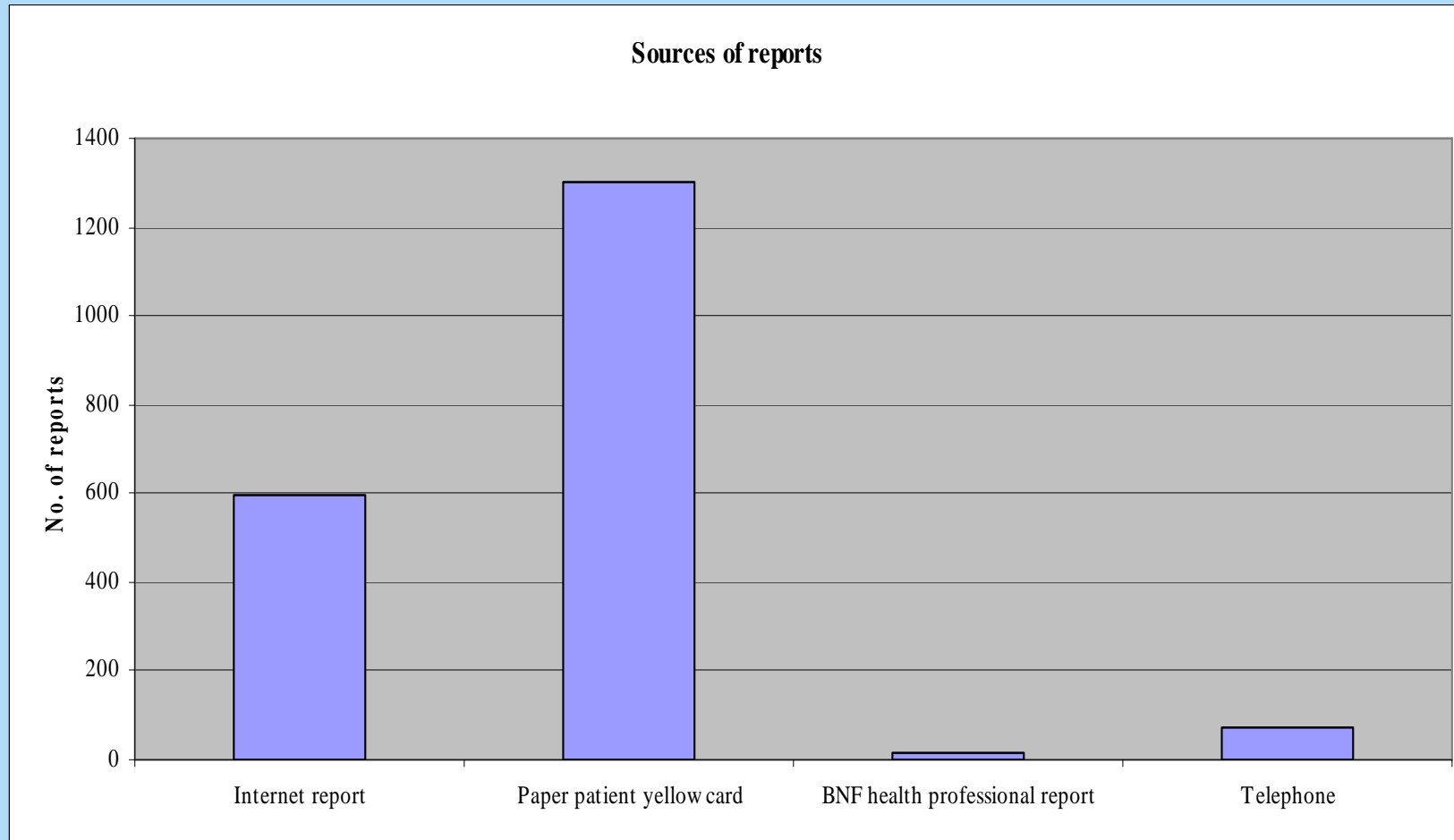
Cumulative total received

> 3,159 patient reports since Jan 2005

Peaked

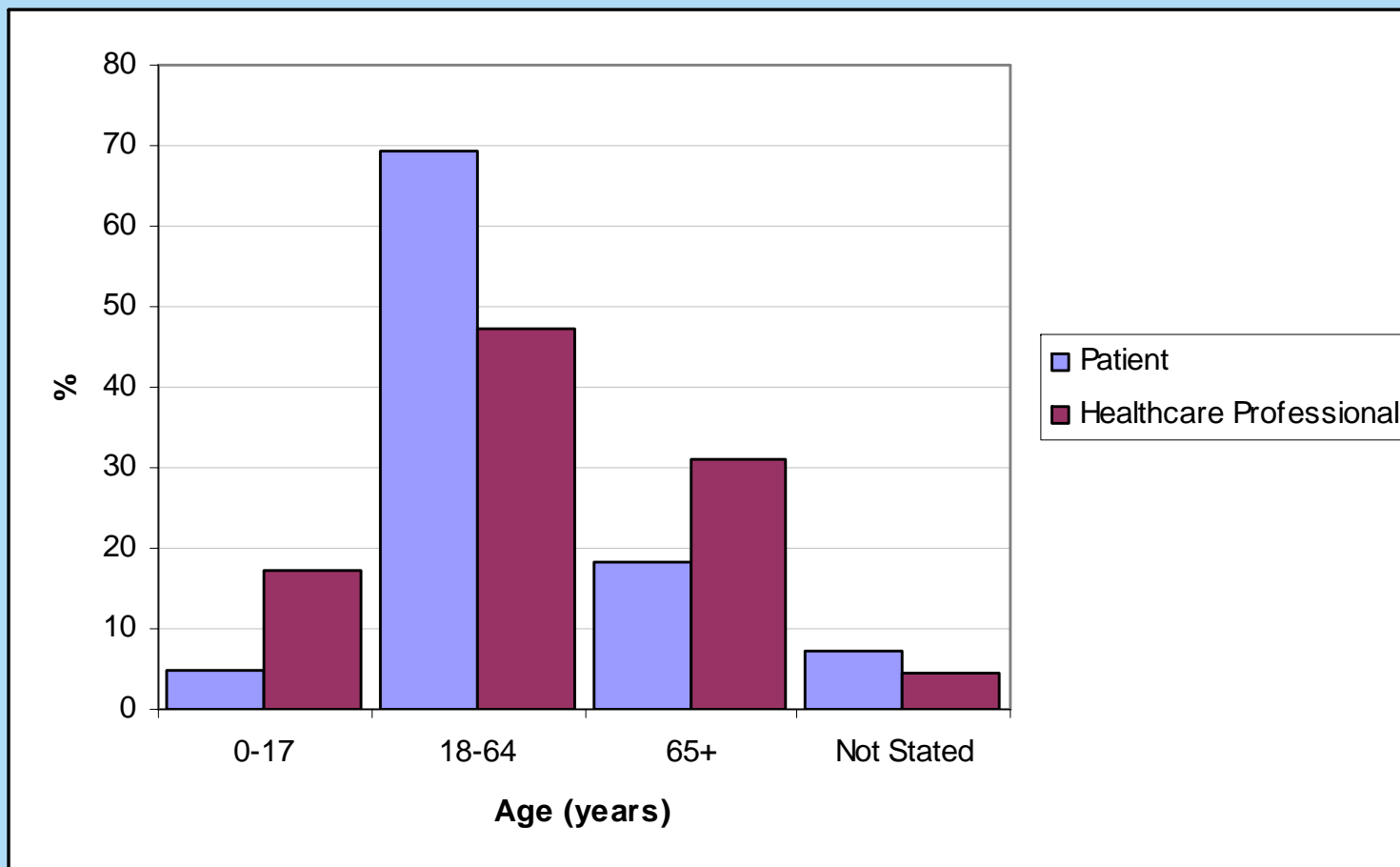
at >500 reports per month

Source of Reports

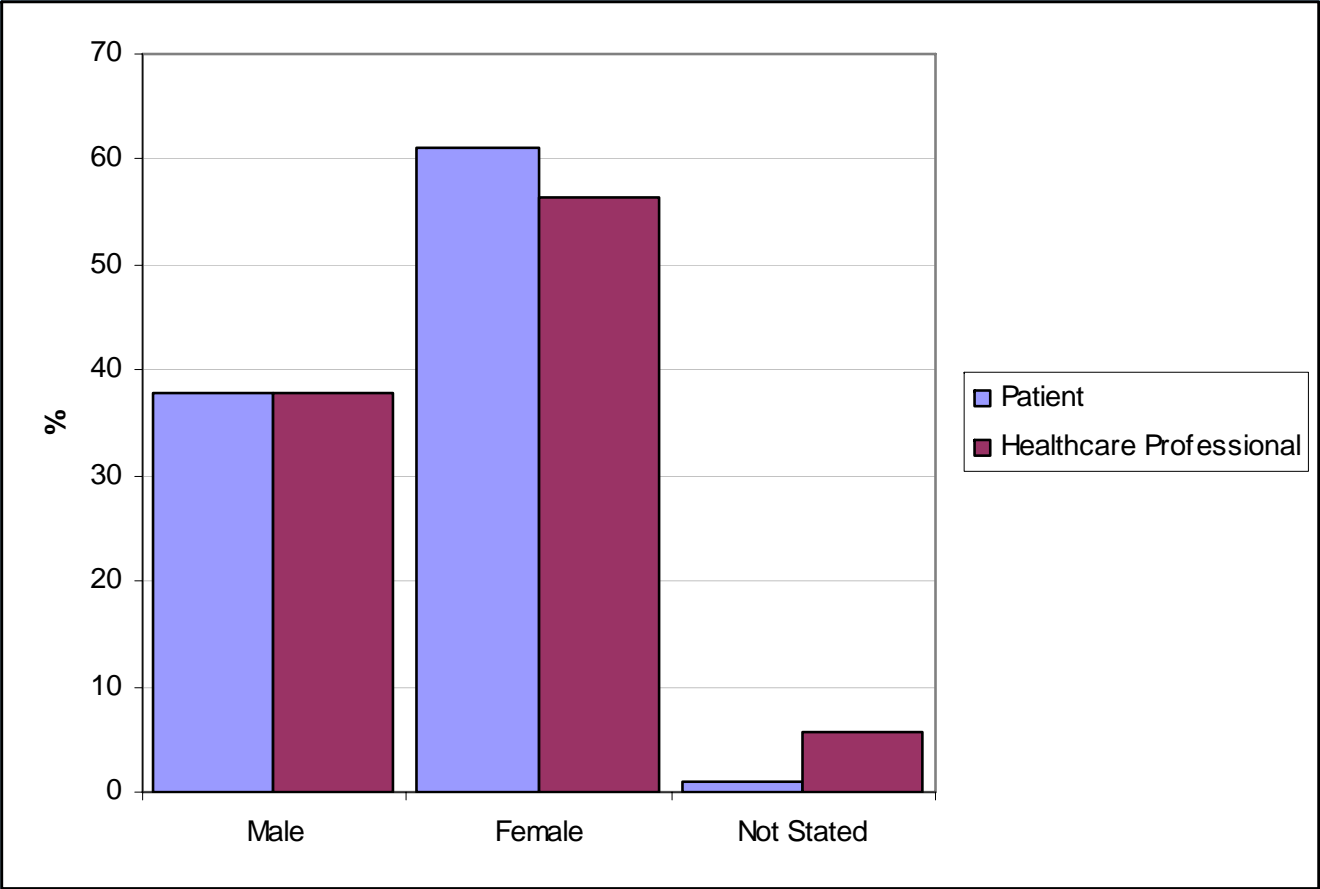


Age Breakdown

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Gender Breakdown



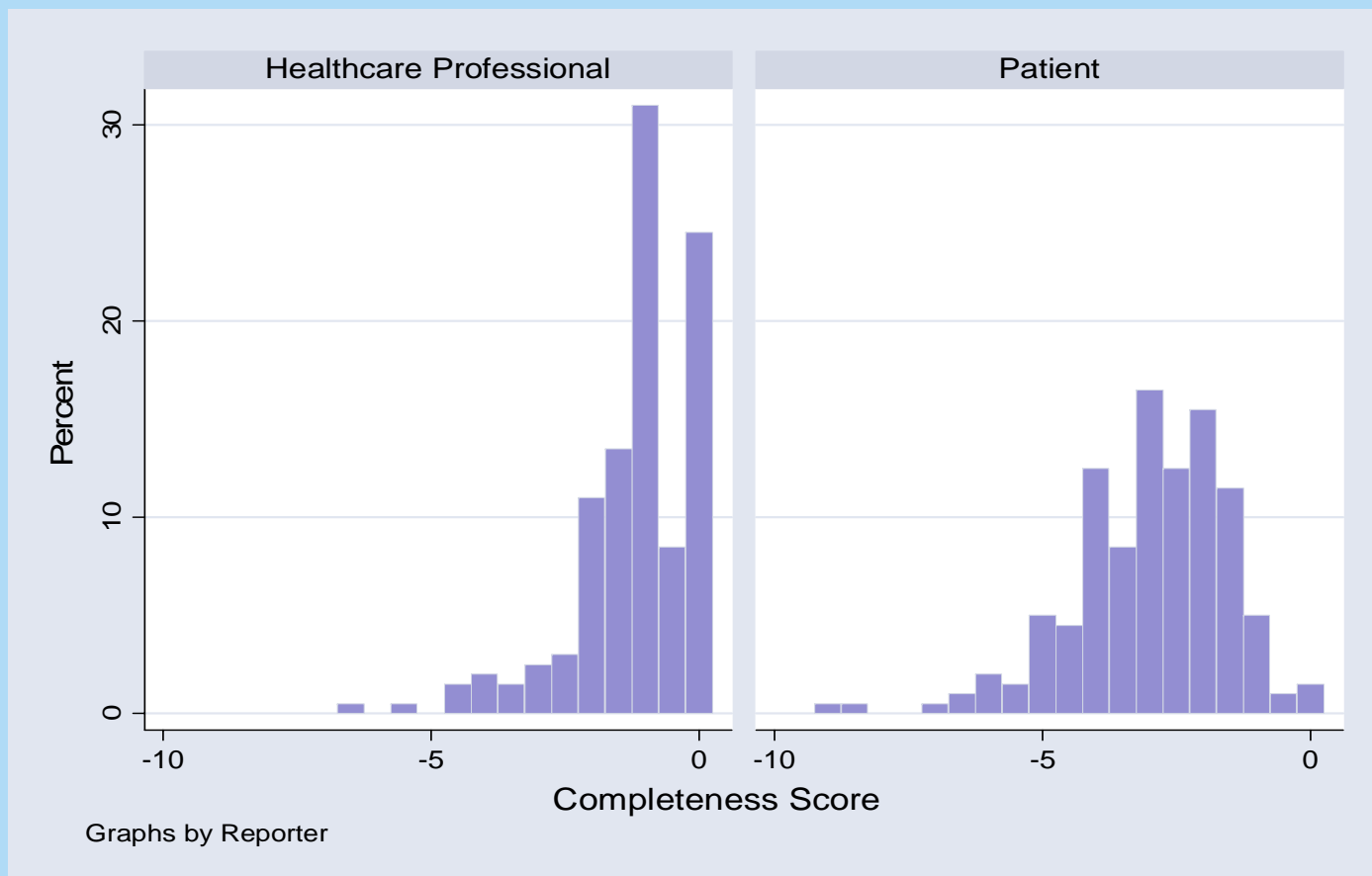
Top 5 Most Frequently Reported Drugs

<i>Patient</i>		<i>Healthcare Professional</i>	
Drug Name	No. (%)	Drug Name	No. (%)
Paroxetine	51 (13)	BCG Vaccine	299 (4)
Venlafaxine	17 (4)	DTap IPV Vaccine	261 (4)
Diclofenac	15 (4)	Pregabalin	192 (3)
Simvastatin	13 (3)	Duloxetine	135 (2)
Amoxicillin	11 (3)	Bupropion	129 (2)

Top 5 Most Frequently Reported Reactions

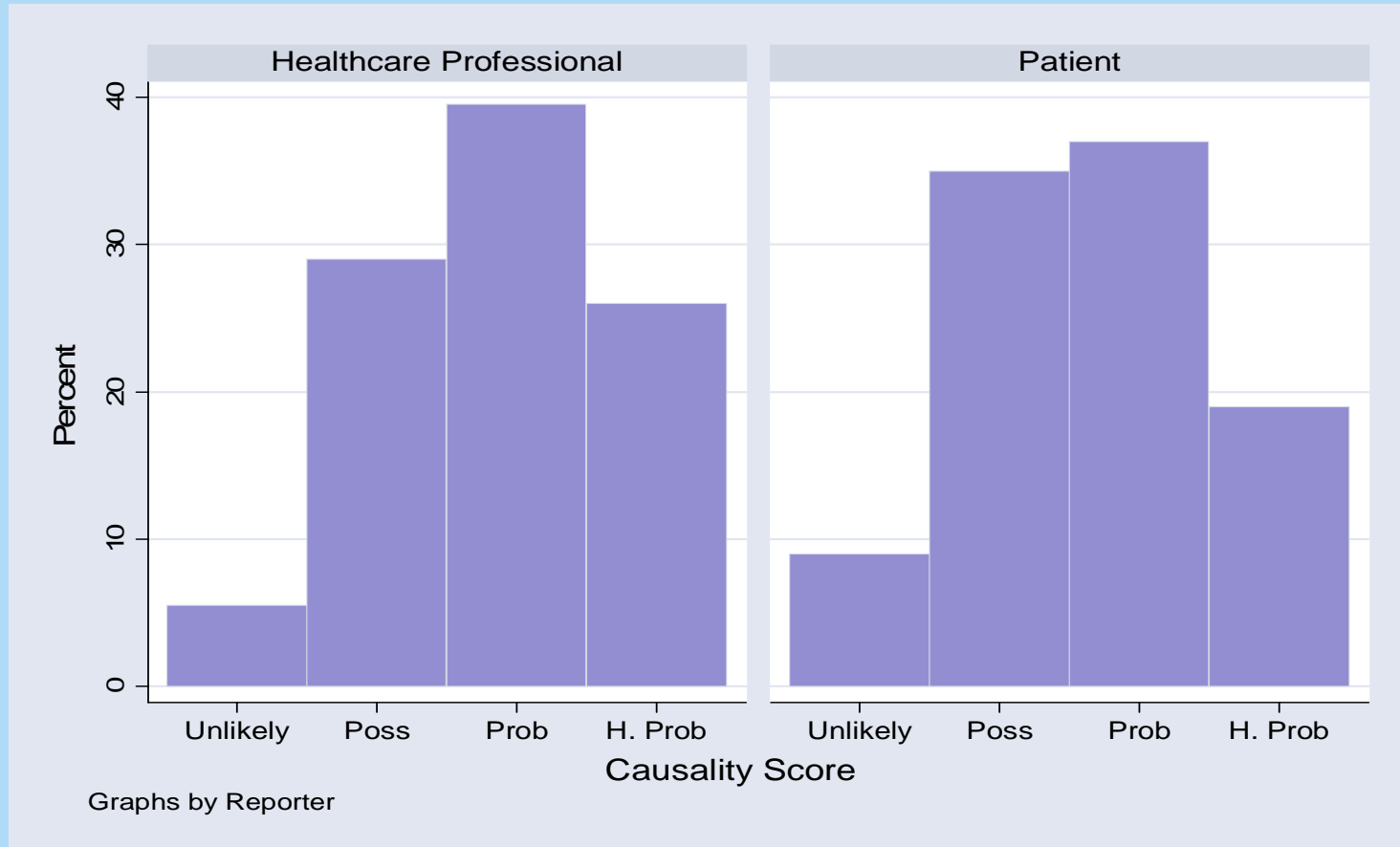
<i>Patient</i>		<i>Healthcare Professional</i>	
Drug Name	No. (%)	Drug Name	No. (%)
Dizziness	55 (14)	Dizziness	276 (4)
Headache	44 (11)	Nausea	270 (4)
Nausea	43 (11)	Headache	261 (4)
Drug Withdrawal Syndrome	41 (10)	Erythema	210 (3)
Malaise	36 (9)	Rash	200 (3)

Completeness Assessment



- Healthcare professional reports are generally more complete than patient reports

Causality Assessment



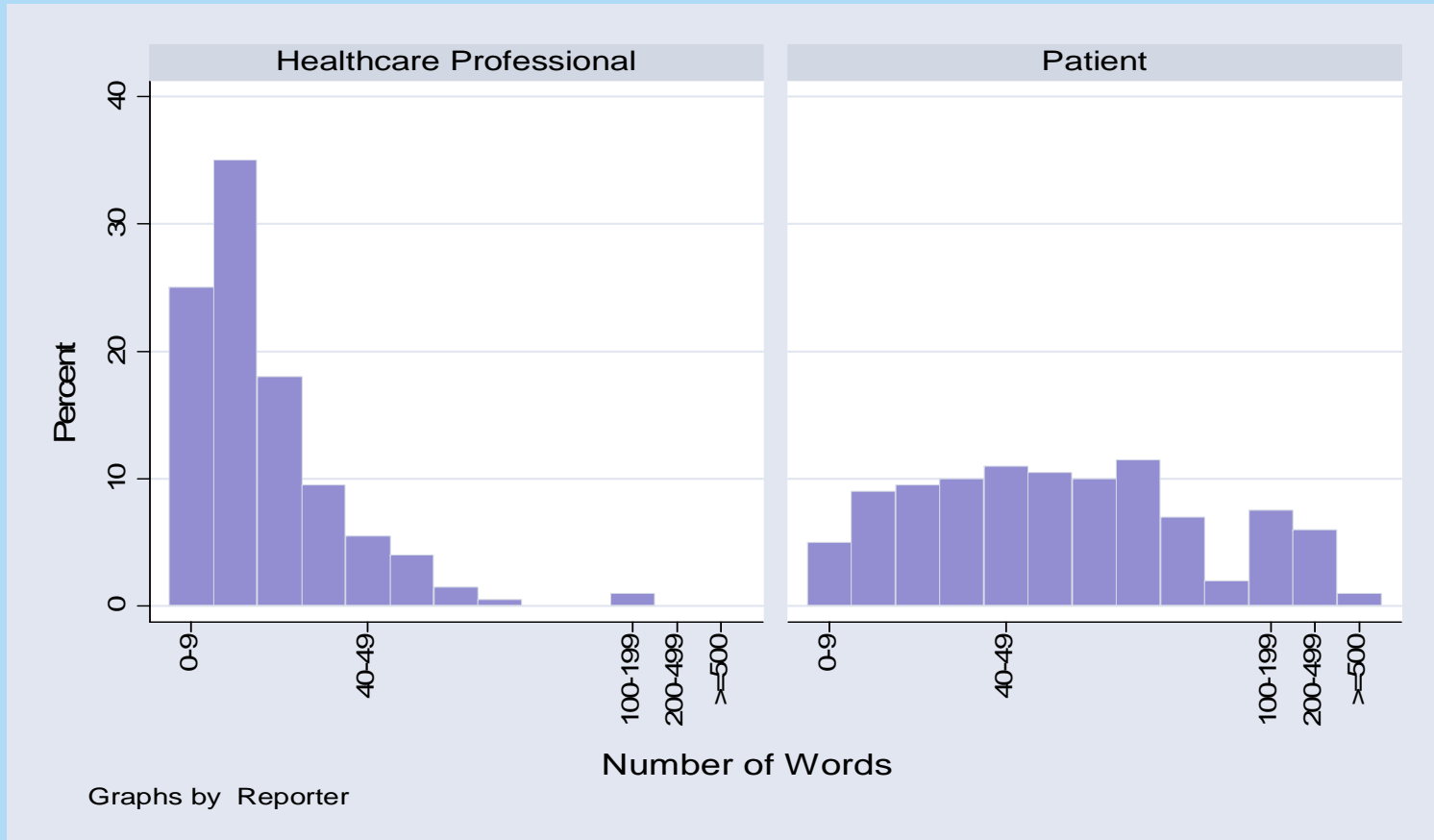
- No difference in causality between healthcare professional and patient reports

Reports Concerning 'New' ADRs

	Healthcare Professional	Patient
Labelled Reaction	155 (77%)	156 (78%)
Unlabelled Reaction	45 (23%)	44 (22%)

- No difference in the proportion of reports for unlabelled 'new' ADRs between patient reports and healthcare professional reports

Word Count



- Patients use many more words to describe ADRs compared with healthcare professionals

What happens to Patient Yellow Cards

- Patient reports are treated identically to HCP reports
- Validation / reply to reporter
- Prioritisation
 - Serious, fatal, Black Triangle
 - “Issues”
- Entry onto database
- Assessment / follow up communication
- Duplicate identification
- Signal detection and evaluation processes

Patient reports in Signal Detection

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- A signal is information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously
- Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information
- Can arise from any data source

Pre-clinical data, Laboratory investigations, Clinical trials, Epidemiological studies, spontaneous reports

- Further evaluation required

Signal Evaluation - Steps

- Signal identified from any source
- Next steps: Signal evaluation
 - Case review
 - Other data sources
 - Evidence Strength & public health impact
 - Weekly scoping/escalation meeting
 - Epidemiologist/assessor risk (benefit) assessment
 - Commission advice

Next Steps Patient reporting: Evaluation

The NHS R&D & MHRA call for proposals for an evaluation of the patient reporting component of the Yellow Card System

Patient Experience

- Patient awareness of being able to report
- The relative effectiveness of different communication strategies to encourage patient reporting
- Patients' reactions to the reporting system and ability to complete Yellow Cards without assistance
- Patients' views of the user friendliness, effectiveness and usability of different mechanisms of reporting

The NHS R&D & MHRA call

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Pharmacovigilance Impact

- A qualitative investigation of the 'richness' of patient descriptions of their symptoms
- The time-lag between ADR occurrence and reporting
- The relative contribution of patient reporting to signal generation in terms of both quantity and quality (i.e. do patient reports capture new knowledge? What proportion are serious?)



Further advice

Commission on Human Medicines Patient Information expert advisory group

- To advise on facilitation and promotion of patient reporting

Yellow Card runner-up in Ask About Medicines Awards for Excellence 2006

category “Excellence in providing medicines information to medicines users and the public”

Ask About Medicines was launched in 2003 and its objective is to enable people in the UK to make informed choices about medicine taking. More information is available on the [Ask About Medicines website](#)

Acknowledgements

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